II. Remarks

A. Status of the Claims

Claims 13-24 and 58-59 are currently pending. Claims 1-12 and 25-56 were previously cancelled. Claim 57 has been cancelled without prejudice. Claims 13, 16, 23 and 24 have been amended without prejudice. New claims 58 and 59 have been added. Applicants submit that no new matter has been added by virtue of this amendment.

B. New Claim Rejections Under 35 U.S.C. § 112, first paragraph

In the Office Action, claims 13-24 and 57 were rejected under 35 U.S.C. § 112, first paragraph for allegedly failing to comply with the written description requirement. Specifically, the Examiner stated that "the specification provides insufficient written description for the composition(s) of the pharmaceutical dosage forms that provide release profiles as claimed in the instant application. Applicant has not provided a description as to how a dosage form that meets the functional limitations of the claims are formulated."

When read in its entirety, i.e., the description along with the Examples and the Figures, the present specification meets the written description requirements as set forth in the MPEP, as it "describe[s] the claimed invention in sufficient detail [so] that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention". MPEP 8th Ed. 7th Rev., § 2163.

Applicants respectfully draw the Examiner's attention to paragraphs [0019]-[0021] of the present specification, which provide direct support for the dissolution profiles of the claimed compositions. Figures 1-5 provide *in vitro* dissolution profiles of formulations which meet the claimed criteria. Additionally, the detailed description provides examples of coatings, polymers, etc., which may the used in the claimed compositions and the specification provides nine examples, beginning on page 32, which exemplify the types of formulations contemplated by the present invention. The Examiner has acknowledged the presence of the Examples and Figures, but stated that

Examples do not provide release profile information and the Figures do not give the composition of the formulations referred to therein. Applicants submit that the Examiner is viewing the application in segments – not in its entirety -- and is not considering what the application teaches as a whole.

Furthermore, "[t]here is a strong presumption that an adequate description of the claimed invention is present when the application is filed" and "[t]he Examiner has the initial burden, after a thorough reading and evaluation of the content of the application, in presented evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims." Id., citing *In re Wertheim*, 541 F.2d 257, 263 (CCPA 1976). Applicants submit that the instant application provides adequate description for the functional limitations of the claimed compositions and how such compositions are formulated, and the Examiner has not met her burden as no evidence or reasoning is provided as to why a person skilled in the art would not recognize that the written description of the invention provides support for the claims.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph be removed.

C. Claim Rejections Under 35 U.S.C. § 103(a)

1. Sunshine et al. in view of Vishwanathan et al.

In the Office Action, claims 13-16, 20, 21, 23, 24 and 57 were rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 4,780,463 (Sunshine et al.) in view of U.S. Publication No. 2002/0119192 (Vishwanathan et al.) on the grounds that "[i]t would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a dosage form containing both immediate and sustained release baclofen, as taught by Sunshine et al., and to use the controlled release polymers taught as suitable for the controlled release of baclofen, taught by Vishwanathan et al. to prepare the controlled release portion of the dosage form."

Applicants point out that the claims have been amended herein with the intent to exclude the polymers taught by Vishwanathan et al., namely carboxyvinyl polymer. Sunshine et al. fails to appreciate the unique absorption profile of baclofen and fails to provide any guidance to a skilled artisan on how to formulate a sustained release baclofen formulation, i.e., a baclofen formulation having the claimed dissolution profile. The skeletal muscle relaxants that are contemplated by Sunshine et al. to be in sustained release form are listed in Table IV, and are limited to diazepam, chlorzoxazone, carisoprodol, methocarbamol and orphenadrine citrate. Baclofen is not included in this list.

Applicants submit that Vishwanathan et al. in combination with Sunshine et al. actually teaches away from the present invention; the principle operation of Vishwanathan et al. is to "selectively release the drug in a controlled manner at the gastric levels and upper parts of the intestine over a prolonged period of time" and this is achieved via a "polymeric matrix characterized in that at least one such polymer is carboxyvinyl polymer". Vishwanathan et al. at paragraphs [0020]-[0021] (emphasis added). The polymers of Vishwanathan operate primarily as a type of 'gastro retentive mechanism.' Applicants submit that the inclusion of carboxyvinyl polymer of Vishwanathan et al. into the controlled release component of the present dosage form would materially change the characteristics of the present invention, i.e., by causing release mainly in the upper gastrointestinal tract, as opposed to the intended release in the lower gastrointestinal tract.

In view of the amendments made to the claims (to exclude the carboxyvinyl polymer of Vishwanathan et al.) and the arguments made above, Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) over Sunshine et al. in view of Vishwanathan et al. be removed.

2. Sunshine et al. in view of Vishwanathan et al. further in view of Fara et al.

In the Office Action, claims 13 and 17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sunshine et al. in view of Vishwanathan et al. as applied above, further in view of U.S. Patent application No. 2003/0031711 (Fara et al.).

This rejection is traversed. Fara et al. is cited by the Examiner solely for the discussion of racemic baclofen and therefore do not cure the deficiencies of Sunshine et al. in view of Vishwanathan et al. In fact, Applicants point out that Fara et al. present the same issue that Vishwanathan et al. presents in that it is directed to "a gastric retentive drug delivery formulation" of baclofen, i.e., the type of dosage form the present inventors have avoided by creating the presently claimed dosage form. See, e.g., Fara et al., Examples 3 and 4.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) over Sunshine et al. in view of Vishwanathan further in view of Fara et al. be removed.

3. Sunshine et al. in view of Vishwanathan et al. further in view of Patel et al.

In the Office Action, claims 13, 23 and 24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sunshine et al. in view of Vishwanathan et al. as applied above, further in view of Patel et al.

Patel et al. is relied upon solely for teaching capsules comprising discreet units and does not cure the deficiencies of Sunshine et al. in view of Vishwanathan et al. as discussed above.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) over Sunshine et al. in view of Vishwanathan further in view of Patel et al. be removed.

III. Conclusion

In view of the amendments made and arguments presented, it is believed that all claims are in condition for allowance. If the Examiner believes that issues may be resolved by a telephone interview, the Examiner is invited to telephone the undersigned at (973)597-6162. The undersigned also may be contacted via e-mail at epietrowski@lowenstein.com. All correspondence should be directed to our address listed below.

AUTHORIZATION

The Commissioner is hereby authorized to charge any fees that may be required, or credit any overpayment, to Deposit Account No. 50-1358.

Respectfully submitted,
Lowenstein Sandler PC

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